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K010174

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Premarket Notification [510(k)] Summary
Tab 4

January 5, 2001

Trade Name: Tray Adapters, Multiple

Common Name: Tray Adapters for Radiation Therapy

Classification Name: Medical Linear Accelerator Accessory, 90 IYE (per 21 CFR section 892.5050)

Manufacturer's Name: Arplay Medical S.A.
Address: 1 Route de Citeaux
21110 Izeure
France

Corresponding Official: Richard Borgi, MD
Title: President and CEO
Telephone: +33-3-8029 7401
Fax: +33-3-8029 7622

Predicate: MED-TEC, Inc., Tray Adapter, K950075

Device Description: Arplay Medical Tray Adapters, Multiple, are accessories for radiation therapy to adapt the radiation therapy unit to utilize beam blocks designed to define the radiation field for different unit or to utilize accessories in the treatment field not provided with the original radiation therapy unit. They are designed and machined to meet the individual specifications of the tray mounts or collimators of all brands and models of linear accelerators and cobalt treatment machines. The customer must specify the manufacturer and model of the treatment unit utilizing the adapter and, when they want to use beam modifying accessories made for another manufacturer and/or model, the customer must also specify the make and model of the originating radiation therapy machine.

Tray Adapters are available for all models of linear accelerators, cobalt units and simulators.

The Tray Adapters are manufactured from aluminum and may contain steel and plastic components. They can be supplied with optional coded connectors if required by the customer.

Intended Use: Accessories for radiation therapy to adapt the radiation therapy unit to utilize beam blocks designed to define the radiation field for different unit or to utilize accessories in the treatment field not provided with the original radiation therapy unit.

AFAQ ISO 9002

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Technological Characteristics: See the attached predicate comparison table.

#	Feature	MED-TEC, Inc., Tray Adapter, K950075	Arplay Medical Tray Adapters, Multiple
1	Materials	Aluminum	Aluminum
2	Compatilability	All brands and models of linear accelerators and simulators	All brands and models of linear accelerators, simulators, and cobalt treatment machines
3	Compression Adapter	No	Yes

The Arplay Medical Tray Adapters have the same intended use and performance characteristics as the predicate device. No new issues of safety of effectiveness are introduced by this device.

Société Anonyme au capital de 1.800.000 F • R.C.S. Auxonne B 308 365 766 (B 11) • SIRET 308 365 766 00010 • NAF 331 B
21110 IZEURE • France • tel : 33 (0) 3 80 29 74 01 • fax : 33 (0) 3 80 29 76 22 • http://www.arplay.com • e-mail:arplay.izeure@wanadoo.fr

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 1 8 2001

Richard Borgi, M.D.
President and CEO
Arplay Medical S.A.
1Route de Citeaux
21110 Izeure
FRANCE

Re: K010174
Tray Adapters, Multiple
Dated: January 5, 2001
Received: January 18, 2001
Regulatory Class: II
21 CFR §892.5050/Procode: 90 IYE

Dear Dr. Borgi:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

Tab 3

Indications For Use

510(k) Number: K010174

Device Name: Tray Adapters, Multiple

Indications for Use:
Accessories for radiation therapy to adapt the radiation therapy unit to utilize beam blocks designed to define the radiation field for different unit or to utilize accessories in the treatment field not provided with the original radiation therapy unit.

(PLEASE DO NOT WRITE BELOW THIS LINE)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use___
(per 21 CFR 801.109)

David G. Segmon

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K010174